NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC) GUIDELINE SYNTHESIS

DIAGNOSIS AND TREATMENT OF OBESITY AND OVERWEIGHT IN ADULTS

Guidelines

1. **American College of Physicians (ACP)**. Pharmacologic and surgical management of obesity in primary care: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2005 Apr 5;142(7):525-31. [43 references]
2. **Singapore Ministry of Health (SMOH)**. Obesity. Singapore: Singapore Ministry of Health; 2004 Apr. 108 p. [253 references]
3. **Department of Veterans Affairs, Department of Defense (VA/DoD)**. VA/DoD clinical practice guideline for screening and management of overweight and obesity. Washington (DC): Department of Veterans Affairs, Department of Defense; 2006. 117 p.

INTRODUCTION

A direct comparison of the American College of Physicians (ACP), Singapore Ministry of Health (SMOH), and the Department of Veterans Affairs/Department of Defense (VA/DoD) recommendations for evaluation/diagnosis and treatment of overweight and obesity in adults is provided in the tables below.

The comparisons given in the tables are restricted to recommendations for assessment and management of overweight and obesity in the adult population only. Recommendations concerning overweight and obesity in children and adolescents are compared in a separate synthesis, Overweight and Obesity in Children and Adolescents: Assessment, Prevention, and Management.

- Table 1 provides a quick-view glance at the primary interventions considered by each group.
- Table 2 provides a comparison of the overall scope of the guidelines.
- Table 3 provides a more detailed comparison of the specific recommendations offered by each group for the topics under consideration in this synthesis, including:
  - Evaluation/Diagnosis
  - Treatment/Management
    - Assessment
    - Treatment Strategy
    - Dietary Interventions
    - Physical Activity
    - Behavior Modification

        - Pharmacotherapy
        - Bariatric Surgery
    - Follow-Up/Maintenance of Weight Loss
- Table 4 lists the potential benefits and harms associated with the implementation of each guideline as stated in the original guidelines.
- Table 5 presents the rating schemes used to rate the level of evidence and/or the strength of the recommendations.

Following the content and recommendation comparison tables, the areas of agreement and areas of differences among the guidelines are identified.

Abbreviations used in the text and table

- ACP, American College of Physicians
- BMI, body mass index
- CAD, coronary artery disease
- DJD, degenerative joint disease
- DoD, Department of Defense
- LCD, low calorie diet
- MAOI, monoamine oxidase inhibitors
- NHLBI, National Heart, Lung, and Blood Institute
- RYGB, Roux-en-y Gastric Bypass
- SMOH, Singapore Ministry of Health
- SSRI, selective serotonin reuptake inhibitors
- USPSTF, United States Preventive Services Task Force
- VHA, Veterans Health Administration
- VLCD, very low calorie diet
- WHO, World Health Organization

TABLE 1: COMPARISON OF INTERVENTIONS AND PRACTICES CONSIDERED
("✓" indicates topic is addressed)

	ACP (2005)	SMOH (2004)	VA/DoD (2006)
Evaluation/Diagnosis		✓	✓
Treatment/Management			
Assessment		✓	✓
Treatment Strategy		✓	✓
Dietary Interventions	✓	✓	✓
Physical Activity	✓	✓	✓

Behavior Modification		✓	✓
Pharmacotherapy	✓	✓	✓
Bariatric Surgery	✓	✓	✓
FOLLOW-UP/MAINTENANCE OF WEIGHT LOSS		✓	✓

TABLE 2: COMPARISON OF SCOPE AND CONTENT	
Objective and Scope	
ACP (2005)	• To provide recommendations based on a review of the evidence on pharmacologic and surgical treatments of obesity • To complement the guidelines on screening for obesity developed by the USPSTF
SMOH (2004)	• To assist health care professionals who have a role in managing overweight or obese patients • To provide current evidence-based clinical practice recommendations on various aspects of obesity management found across various medical disciplines • To provide a framework to assist doctors in the management of overweight and obesity without restricting the physician's individual judgment • To provide a review of the various medical, surgical, and ancillary intervention modalities in the management of obesity • To aid primary care physicians in basic management of obesity and subsequent referrals to specialists for more resistant cases
VA/DoD (2006)	• To describe the critical decision points in the management of obesity • To provide a clear and comprehensive guideline incorporating current information and evidence based practice recommendations for practitioners throughout the Department of Defense and Veterans Health Administration system • To improve local management of patients with obesity and improve patient outcome
Target Population	
ACP	• United States

(2005)	• Patients with a body mass index (BMI) ≥30 kg/m^2 **Note**: The target patient populations vary according to the intervention under consideration, since pharmacologic and surgical trials have used different selection criteria with differing BMIs and comorbid conditions. This guideline does not apply to patients with BMIs below 30 kg/m^2
SMOH (2004)	• Singapore • Adults in Singapore who are obese or overweight, or who are at risk of obesity **Note**: Children and adolescents are also considered in this guideline; recommendations concerning these younger age groups are covered in a separate synthesis, Overweight and Obesity in Children and Adolescents: Assessment, Prevention, and Management.
VA/DoD (2006)	• United States • Adults (age 18 years or older) with overweight or obesity who are eligible for care in the VA or DoD health care delivery system **Note**: This guideline is not directed to the treatment of children, adolescents (less than age 18) or pregnant/lactating women.
Intended Users	
ACP (2005)	Advanced Practice Nurses Allied Health Personnel Nurses Physician Assistants Physicians
SMOH (2004)	Advanced Practice Nurses Allied Health Personnel Dietitians Nurses Physician Assistants Psychologists/Non-Physician Behavioral Health Clinicians Public Health Departments Respiratory Care Practitioners
VA/DoD (2006)	Advanced Practice Nurses Nurses Physician Assistants Physicians

TABLE 3: COMPARISON OF RECOMMENDATIONS FOR DIAGNOSIS AND TREATMENT OF OVERWEIGHT AND OBESITY
EVALUATION/DIAGNOSIS

ACP (2005)	No recommendations offered.
SMOH (2004)	**Diagnosis & Clinical Evaluation** **B** - BMI is the recommended index to define overweight and obesity. It is minimally correlated with height and highly correlated with body fat percentage and levels of disease risk of comorbidities. Body weight alone can be used to follow weight loss and to determine efficacy of therapy. **(Grade B, Level III)** **C** - Current WHO and international guidelines recommend BMI cutoffs of 25 and 30 kg/m^2 to define overweight and obesity, respectively. Based on body fat equivalence and comorbid disease risk, BMIs of 23 and 27.5 kg/m^2, respectively have been recommended as cutoff points for public health action in Asians. **(Grade C, Level IV)** *Note*: BMI cutoff points are currently being reviewed in the light of new data. **B** - Waist circumference is the most practical anthropometric measurement for assessing a patient's abdominal fat content before and during weight loss treatment. Gender-specific waist circumference cutoffs should be used in conjunction with BMI to identify increased disease risk. **(Grade B, Level III)** **C** - Current international guidelines recommend waist circumference cutoffs of 102 and 88 cm to define excess risk in males and females, respectively. Based on an Asian-Pacific consensus and our National Health Survey and comorbid disease risk, cutoffs of 90 and 80 cm, respectively, are probably more appropriate for Asians. **(Grade C, Level IV)**
VA/DoD (2006)	**Obtain Height and Weight; Calculate BMI** *Recommendations:* Adult patients should have their BMI calculated from their height and weight to establish a diagnosis of overweight or obesity. **[B]** Obese patients (BMI >30 kg/m^2) should be offered weight loss treatment. **[B]** Overweight patients (BMI between 25 and 29.9 kg/m^2) or patients with increased waist circumference (>40 inches for men; >35 inches for women) should be assessed for the presence of obesity-associated conditions that are directly influenced by weight, to determine the benefit they might receive from weight loss treatment. **[B]** **Obtain Waist Circumference Measurement**

	Recommendations For screening purposes, waist circumference should be obtained in patients with a BMI <30 kg/m^2 as a predictor of disease risk. **[C]** The waist circumference measurement should be made with a tape measure placed above the iliac crest and wrapped in a horizontal fashion around the individual's abdomen at the end of a normal expiration. Gender-specific cut-offs should be used as indicators of increased waist circumference. **[C]** • Men: waist circumference >40 inches (102 cm) • Women: waist circumference >35 inches (88 cm)
TREATMENT/MANAGEMENT	
Assessment	
ACP (2005)	No recommendations offered.
SMOH (2004)	**GPP** - In clinical evaluation of patients, practitioners should consider and exclude predisposing factors for, and secondary causes of, obesity. **(GPP)** <u>Clinical Risks of Obesity</u> Patient assessment should incorporate evaluation for the many comorbid conditions associated with obesity, such as: • Risk factors for cardiovascular disease including hypertension, diabetes mellitus, hyperlipidaemia, cigarette smoking • Coronary heart and cardiovascular disease • Polycystic ovarian disease • Psteoarthritis • Cancers • Sleep apnea **C** - Overweight and obese adults should be screened for comorbid conditions and should be stratified according to their health risks, in particular for cardiovascular disease, prior to the commencement of treatment. **(Grade C, Level IV)** **Clinical Evaluation** Wherever possible, each patient should be assessed for the degree of

	obesity, predisposing factors, possible underlying secondary causes and potential clinical sequelae. Baseline clinical evaluation should include: <u>History</u> • Detailed history of obesity and previous weight loss attempts • Current motivation for and barriers to weight loss • Current and past medical history, including psychiatric history • Current and past medical therapy, including over-the-counter and traditional medications • Lifestyle factors, including details on dietary habits, exercise, smoking and alcohol intake • Family history of medical disease and obesity • Social history, including family, co-worker and financial support <u>Physical Examination</u> • Weight & height • Calculate: BMI = weight ÷ height^2 (measured in kg/m^2) • Waist circumference • Hip circumference (optional) • Blood pressure • Physical examination for evidence of goiter, Cushing's syndrome, hypogonadism and dysmorphism **Laboratory Evaluation** • Fasting lipids • Fasting blood glucose • Thyroid function tests: free T4, TSH • For Cushing's syndrome if clinically suspected, or if there is a history of weight gain with unaccounted medication, including traditional medicines: refer to endocrinologist for evaluation • Electrocardiogram • Chest radiograph **C** - Patient motivation is an important prerequisite of weight loss management and should be relatively high before initiating therapy. Proper evaluation of issues related to motivation should be undertaken. **(Grade C, Level IV)** **B** - The presence of depression and binge eating disorders in obese patients must be evaluated with appropriate referral for psychiatric treatment. **(Grade B, Level IIa)**
VA/DoD (2006)	**Obtain Medical History, Physical Examination, and Laboratory Tests as Indicated** The clinical assessment of the overweight or obese patient should be

	done by the primary care provider. The assessment should include a basic medical history, a relevant physical examination, and laboratory tests as clinically indicated. The history should include age of onset or periods of rapid increase in body weight, precipitating factors, and maximum lifetime weight. **[Expert Opinion]** The clinical assessment should rule out organic and drug related causes and identify health risks and/or the presence of weight-related conditions. **[Expert Opinion]** In addition to a medical assessment, a social and psychological assessment may be indicated to identify barriers to participating in dietary or physical activity programs. The assessment may also include screening for behavioral health conditions that may hinder successful weight loss (i.e., depression, post-traumatic stress disorder, anxiety, bipolar disorder, addictions, binge eating disorder, bulimia, and alcoholism). **[Expert Opinion]** A nutritional evaluation should include an assessment of current intake as well as the use of supplements, herbs, and over-the-counter weight loss aides. In addition, meal and snack patterns and problem eating behaviors need to be assessed. The weight and dieting history should include the age of onset of weight gain, number and types of diets and attempts, possible triggers of weight gains and losses, and range of weight change. **[Expert Opinion]** Current levels of physical activity and sedentary lifestyle should be assessed, including exercise frequency, duration, and intensity as well as the patient's motivation to increase physical activity. **[Expert Opinion]** **Assess Patient's Readiness to Lose Weight** Readiness to lose weight should be assessed by direct inquiry. Those indicating an adequate readiness to lose weight (preparation or action stage) should proceed to treatment. Those not yet ready to lose weight (precontemplation or contemplation stage) should receive motivational counseling. **[Expert Opinion]**
Treatment Strategy	
ACP (2005)	No recommendations offered.
SMOH (2004)	**C** - A multifaceted or multidisciplinary strategy should be utilized to achieve and maintain weight loss. Depending on patient response, this could be adequately achieved at the primary health care level or tertiary level. **(Grade C, Level IV)** **A** - The combination of dietary caloric restriction, physical activity and

	behavioural modification results in greater and more sustained weight loss than the individual modalities. **(Grade A, Level Ib)** **C** - It is important to set realistic goals for weight loss and provide sound advice on lifestyle modification. Modest weight loss (e.g., 10% body weight over 6 months) is more realistic and attainable than aiming for weight reduction to ideal body weight and does result in a reduction in obesity morbidity. **(Grade C, Level IV)**
VA/DoD (2006)	**Reach Shared Decisions About Goals and Treatment Plan** The clinical team, together with the patient, should reach shared decisions regarding the treatment program. **[Expert Opinion]** • The clinical team should convey to the patient that obesity is a chronic disease that will require lifelong treatment • The clinical team should suggest the personalized preferred treatment options based on disease risk and patient characteristics (e.g., describe to the patient/caregiver the treatment options, including behavioral modification, diet and activity patterns, prognosis, estimated length and frequency of therapy, and expectations) • The patient should describe his or her needs, preferences, and resources and assist the team in determining the optimal environment for therapy and preferred interventions • The patient and the clinical team together should reach conclusions on the goals of therapy and preferred treatment plan The patient's family/caregiver may participate in the treatment process and should be involved in assisting the patient with changing lifestyle, diet and physical activity patterns. **[Expert Opinion]** A detailed treatment plan needs to be documented in the medical record to provide integrated care. **[Expert Opinion]** **Initiate Interventions Based on Risk Level and Patient Preferences** Weight loss therapy should be tailored to risk level based on calculated BMI and based upon the balance of benefits and risks and patient preferences. **[C]** Patients who may benefit from weight loss should be offered interventions to improve their diet, increase exercise, and change related behaviors to promote weight loss. **[A]** Weight loss interventions should combine dietary therapy, increased physical activity, and behavioral modification strategies rather than utilizing one intervention alone. **[A]**

	A reasonable initial goal of weight loss therapy (intervention) is a 10 percent reduction in body weight. **[B]** Drug therapy in combination with a reduced-calorie diet and exercise interventions should be considered for obese patients (BMI $\geq$30 kg/m^2) or overweight patients (BMI $\geq$27 kg/m^2) with an obesity-associated chronic health condition (i.e., hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, and sleep apnea). **[B]** Bariatric surgery to reduce body weight, improve obesity-associated comorbidities, and improve quality of life may be considered in adult patients with a BMI $\geq$40 kg/m^2 and those with a BMI $\geq$35 kg/m^2 with at least one obesity-associated chronic health condition (i.e., hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, and sleep apnea). **[B]** There is insufficient evidence to recommend drug or surgical interventions specifically for patients who have documented CAD. **[I]** However, there is good evidence that drug and surgical weight loss interventions may improve cardiovascular risk factors, such as hypertension, dyslipidemia, and diabetes mellitus. **[A]** There is insufficient evidence to recommend drug or surgical interventions specifically for patients who have DJD. However, physical activity and diet may improve physical function and chronic pain in patients with DJD. **[I]**
Dietary Interventions	
ACP (2005)	Clinicians should counsel all obese patients (defined as those with a body mass index [BMI] $\geq$30 kg/m^2) on lifestyle and behavioral modifications such as appropriate diet and exercise, and the patient's goals for weight loss should be individually determined (these goals may encompass not only weight loss but also other parameters, such as decreasing blood pressure or fasting blood glucose levels).
SMOH (2004)	**A** - The most important dietary component of weight loss and maintenance is a decrease in caloric intake. Typically, a 500 to 1,000 kcal per day reduction produces the recommended 0.5 to 1 kg per week weight loss. In the absence of physical activity, a diet that contains 1,400 to 1,500 kcal/day, regardless of macronutrient content, results in weight loss. Sustained dietary modification is necessary to maintain weight loss. **(Grade A, Level Ib)** **C** - Diets containing different proportions of the major macronutrients, such as moderate-fat balanced nutrient-reduction diets; high-fat, low-carbohydrate diets; and low- or very-low-fat, high-carbohydrate diets have all been shown to reduce weight. Weight loss appears to be more associated with reduced caloric intake and increased diet duration, rather than the macronutrient content per se. A diet

	moderately restricted in total fat, moderate to high in complex carbohydrates, and moderate in protein is the most widely recommended diet. **(Grade C, Level IV)** **C** - The distribution of food intake should be as even as possible throughout the day, and meals should not be skipped as a weight control method. Meals should be adequately sized so that snacks are not needed between meals. **(Grade C, Level IV)** **A** - LCDs and VLCDs may be useful shorter term adjuncts (up to 6 months) for weight loss, but sustained modification of food intake is necessary to maintain weight loss. The use of these diets as part of a meal replacement strategy appears useful. The combination of a controlled energy diet (LCD or VLCD), increased physical activity, and behaviour therapy appears to provide the most successful outcome for weight loss and maintenance. **(Grade A, Level Ib)** **C** - VLCDs may be considered in patients with BMI $\geq$30 kg/m^2 (commensurate Asian cut-point may be 27.5 kg/m^2), who have failed more conservative weight loss attempts, or those in whom rapid weight loss is a medical necessity. **(Grade C, Level IV)** **C**- VLCDs should be avoided in patients with BMI $\leq$30 kg/m^2 (commensurate Asian cut-point may be 27.5 kg/m^2), where loss of lean body mass may be excessive, children or younger adolescents, and elderly patients over 65 years old, except in specialized treatment programs. **(Grade C, Level IV)** **C** - VLCDs are not recommended for pregnant or breastfeeding women, patients with severe systemic or organ diseases, or with significant psychiatric or eating disorders. **(Grade C, Level IV)**
VA/DoD (2006)	**Diet Therapy** *Recommendations* <u>Weight Loss</u> Dietary interventions should be individually planned, in conjunction with physical activity, to create a caloric deficit of 500 to 1,000 kcal/day. Such negative energy balance may lead to a weight loss of 1 to 2 pounds per week. **[B]** <u>Selection of Specific Diets</u> Dietary programs should at a minimum reduce the usual caloric intake by 500 to 1,000 kcal/day to achieve modest weight loss. **[B]** LCDs should generally include 1,000 to 1,200 kcal/day for women and 1,200 to 1,600 kcal/day for men and should include the major

	nutrients in appropriate proportions (see Appendix C, Table C-1 in the original guideline document). **[B]** VLCDs that restrict calories to less than 800 kcal/day [15 kcal/kg ideal body weight] are not recommended for weight loss, but may be used short term (12 to 16 weeks) under medical supervision. **[B]** Low-fat intake (20 to 30 percent of total calories/day), as part of LCDs, can be recommended to induce weight loss and should be recommended for patients with cardiovascular disease or lipid abnormalities. **[B]** Low-carbohydrate diets (less than 20 percent of total calories) may be used for short-term weight loss, but are not recommended for long-term dieting or weight maintenance. **[B]** Low-carbohydrate diets can be recommended to reduce serum triglyceride levels for overweight patients with mixed dyslipidemia. **[B]** Low-carbohydrate diets are not recommended for patients with hepatic or renal disease or for patients with diabetes who are unable to monitor blood glucose. **[C]** LCDs or VLCDs may include meal replacements (e.g., bars and shakes). **[A]** There is insufficient evidence to recommend for or against a diet limited to foods with a glycemic index less than 55 as a means of producing weight loss. **[C]** <u>Commercial Diets</u> Patients should be encouraged to adhere to a specific diet, as adherence to any diet plan from a variety of programs (e.g., Atkins, Ornish, Weight Watchers, and Zone) has been shown to be the most important factor in achieving weight reduction. **[B]**
Physical Activity	
ACP (2005)	Clinicians should counsel all obese patients (defined as those with a body mass index [BMI] $\geq$30 kg/m^2) on lifestyle and behavioral modifications such as appropriate diet and exercise, and the patient's goals for weight loss should be individually determined (these goals may encompass not only weight loss but also other parameters, such as decreasing blood pressure or fasting blood glucose levels).
SMOH (2004)	**A** - Current physical activity contributes to weight loss, reduces cardiovascular risk factors (e.g., hypertension and diabetes mellitus) and the risk for coronary heart disease, increases cardiorespiratory

	fitness independent of weight loss, and decreases body and abdominal fat. **(Grade A, Level Ib)** **C** - The current recommendation of moderate-intensity physical activity for 30 min, 3 to 5 days per week is largely aimed at reducing cardiovascular disease and overall mortality. **(Grade C, Level IV)** **C** - To prevent unhealthy weight gain, moderate-intensity physical activity for 45 to 60 min on most days or every day has been recommended. Preventing weight gain after substantial weight loss probably requires about 60 to 90 minutes per day. Starting at low-to-moderate physical activity for 30 to 45 min, 3 to 5 days per week, the intensity, duration, and frequency should be increased gradually. **(Grade C, Level IV)** **A** - A program of diet plus non-structured, moderate-intensity lifestyle activity appeared as effective as diet plus structured aerobic activity for reducing weight in obese women. Any increase in daily physical activity is likely to have some benefit in obese women. **(Grade A, Level Ib)**
VA/DoD (2006)	**Physical Activity** *Recommendations* Weight loss interventions should include exercise to promote weight loss **[A]**, maintain weight loss **[A]**, decrease abdominal obesity **[B]**, improve cardiovascular fitness **[A]**, improve cardiovascular outcomes **[A]**, and decrease all-cause and cardiovascular mortality **[B]**. Home fitness/lifestyle activities or structured supervised programs may be effectively used to produce a caloric expenditure leading to weight loss. **[A]** Moderate levels of physical activity should be performed at least 30 minutes most days of the week. **[B]** Physical activity may include short intermittent bursts (10 minutes or longer) as well as longer continuous exercise. **[A]**
Behavior Modification	
ACP (2005)	No recommendations offered.
SMOH (2004)	**A** - Weight loss programs incorporating cognitive behavioural interventions are helpful in achieving weight loss and weight maintenance in the range of up to 10% for between 1 to 5 years of follow-up. **(Grade A, Level Ib)**

VA/DoD (2006)	**Behavioral Modification Strategies** *Recommendations* Behavioral modification interventions to improve adherence to diet and physical activity should be given to overweight or obese individuals. **[B]** Behavioral modification interventions should be provided at a higher intensity when possible for greater effectiveness. Higher intensity is defined as more than one personal contact per month for the first three months (individual or group setting). Less frequent intervention may be an ineffective and inefficient use of manpower. **[B]** Multiple behavioral modification strategies should be used in combination for greater effectiveness. **[A]** Behavioral modification intervention should be delivered in a group format when possible rather than individually. **[B]** For individuals unable or unwilling to participate in weight loss treatment in person, telephone or internet-based behavioral modification intervention may be considered. **[B]** Behavioral modification intervention should be continued on a long-term basis to promote maintenance of weight loss. **[B]**
Pharmacotherapy	
ACP (2005)	• Pharmacologic therapy can be offered to obese patients who have failed to achieve their weight loss goals through diet and exercise alone. However, there needs to be a doctor/patient discussion of the drugs' side effects, the lack of long-term safety data, and the temporary nature of the weight loss achieved with medications before initiating therapy. • For obese patients who choose to use adjunctive drug therapy, options include sibutramine, orlistat, phentermine, diethylpropion, fluoxetine, and bupropion. The choice of agent will depend on the side effects profile of each drug and the patient's tolerance of those side effects. There are no data to determine whether one drug is more efficacious than another, and there is no evidence for increased weight loss with combination therapy. There are no data about weight regain after medications are withdrawn, underscoring the need for sustained lifestyle and behavioral modifications. There are no long-term (>12 months) studies of efficacy or safety to inform the decision to continue treatment beyond 1 year; thus, the decision to continue should be a shared discussion between the physician and patient.

SMOH (2004)	**Medical Treatment** **C** - As obesity is a chronic condition that requires lifelong management, pharmacotherapy should be adjunct to an individual's long-term obesity management strategy (NHLBI Obesity Initiative, 1998). **(Grade C, Level IV)** **A** - Drug therapy may be effective if given without lifestyle modification, but is most effective when combined with diet, physical activity, and behaviour modification. **(Grade A, Level Ib)** **C** - Drug therapy should be considered when BMI $\geq$30 kg/m^2, or when BMI is 27 to 29.9 kg/m^2 in patients with comorbidities or complications of obesity such as hypertension, type 2 diabetes mellitus, hyperlipidemia, coronary artery disease, and sleep apnea. Commensurate BMI thresholds for action among Asians may be 27.5 and 25 to 27.4 kg/m^2, respectively. **(Grade C, Level IV)** **Note:** BMI cutoff points are currently being reviewed in the light of new data. **A** - The drugs with the widest efficacy and safety data are orlistat (up to 4 years) and sibutramine (up to 2 years). Other drugs which appear relatively safe and effective for 6 to 12 month therapy include phentermine and mazindol. There is little data on the effectiveness of combining anti-obesity agents. Metformin is the drug of choice in obese diabetics and has been effectively combined with either sibutramine or orlistat for 1 year. **(Grade A, Level Ib)**
VA/DoD (2006)	**Pharmacotherapy** *Recommendations* Adult patients with a BMI greater than 30 kg/m^2 or a BMI greater than 27 kg/m^2 with obesity-associated conditions may be considered for pharmacotherapy in combination with a reduced-calorie diet, increased physical activity and behavioral therapy. **[B]** Patients who do not respond to medication with a reasonable weight loss should be evaluated for adherence to the medication regimen and adjunctive therapies or considered for an adjustment of dosage. **[I]** If the patient continues to be unresponsive to the medication, or serious adverse effects occur, the use of medication should be discontinued. **[I]** <u>Orlistat</u> Orlistat may be considered to reduce body weight **[B]** and improve obesity-associated cardiovascular risk factors **[C]**.

	Patients who have lost 5 percent or more of their body weight after 12 weeks of treatment or lost an average of 1 pound or more per week with orlistat should continue their current treatment, as they are more likely to experience sustained weight loss. **[B]** Orlistat may be considered as a component of weight maintenance programs for up to 4 years. **[B]** Patients prescribed orlistat should take a multiple vitamin that includes fat soluble vitamins. **[Expert Opinion]** <u>Sibutramine</u> Sibutramine may be considered to reduce body weight **[B]** and improve glycemic and lipid parameters **[C]**. Patients who have lost an average of 1 pound or more per week during the first 4 weeks of therapy with sibutramine should continue treatment, barring any intolerable side effects. **[Expert Opinion]** Patients who fail to lose 4 pounds after 4 weeks treated with sibutramine should have their adherence assessed and, if appropriate, an increase in the dose for an additional 4-week trial. **[I]** Sibutramine may be considered as a component of weight maintenance programs for up to 2 years. **[B]** Sibutramine should be discontinued if it is not efficacious in helping the patient to lose or maintain weight loss. **[B]** Sibutramine should be used with caution as it can elevate blood pressure and heart rate. **[A]** Adult patients with uncontrolled hypertension, cardiovascular disease, or a history of myocardial infarction (MI) or stroke should not include sibutramine as a part of their weight loss program due to the increased risk of harm. **[D]** Sibutramine should be avoided in patients taking SSRIs, MAOIs, triptans, pseudoephedrine, and other agents that affect serotonin. **[D]**
Bariatric Surgery	
ACP (2005)	• Surgery should be considered as a treatment option for patients with a BMI of 40 kg/m^2 or greater who instituted but failed an adequate exercise and diet program (with or without adjunctive drug therapy) and who present with obesity-related comorbid conditions, such as hypertension, impaired glucose tolerance, diabetes mellitus, hyperlipidemia, and obstructive sleep apnea. A

	doctor/patient discussion of surgical options should include the long-term side effects, such as possible need for reoperation, gall bladder disease, and malabsorption. • Patients should be referred to high-volume centers with surgeons experienced in bariatric surgery. • Lifestyle modification through diet and exercise should always be recommended for all obese patients. In addition, patients need to be continuously educated regarding diet and exercise, and it should be clear that after a surgical procedure patients cannot resume their previous eating habits.
SMOH (2004)	**Bariatric Surgery** **A** - Bariatric surgery is the most effective method to reduce weight and maintain weight loss in the severely or morbidly obese. **(Grade A, Level Ib)** **C** - Because surgery has significant technical issues, complications, and cost, and requires extensive pre- and peri-operative preparation, it is usually considered in those with more severe obesity who have failed to control weight by other means and who remain at high risk of medical comorbidities. Post-operative lifestyle modifications, as well as follow-up for complications of surgery, are life-long. **(Grade C, Level IV)** **B** - Indications for considering bariatric surgery are: • Extreme or morbid obesity (BMI $\geq$40 kg/m^2) or severe obesity (BMI $\geq$35 kg/m^2) with medical comorbidities or complications of obesity • Commensurate BMI thresholds for action among Asians may be 37.5 and 32.5 kg/m^2, respectively. • Failure of significant non-surgical attempts at weight reduction **(Grade B, Level III)** **NGC Note**: Refer to the original guideline document for recommendations regarding bariatric surgery and pregnancy.
VA/DoD (2006)	**Bariatric Surgery** *Recommendations* Adult patients with extreme obesity (BMI 40 kg/m^2 or more) or severe obesity (BMI 35 kg/m^2 or more with one or more obesity-associated chronic health condition) may be considered for bariatric surgery to reduce body weight **[A]**, improve obesity-associated comorbidities **[B]**, and improve quality of life **[B]**.

	RYGB is recommended as the bariatric procedure with the most robust evidence for inducing sustained weight loss **[B]** for patients with BMI greater than 40 kg/m^2. There is insufficient evidence to recommend for or against the routine use of bariatric surgery in those over 65 years of age and patients with a substantial surgical risk. **[I]** Providers should engage all patients who are candidates for bariatric surgery in a detailed discussion of the benefits and potential risks of bariatric procedures. **[I]** Relative contraindications to bariatric surgery that are supported only by expert consensus include: • Unstable coronary artery disease, severe pulmonary disease, portal hypertension or other conditions that can compromise anesthesia or wound healing • Patients who are unable to comprehend basic principles of surgery or follow-up postoperative instructions • Patients having had multiple abdominal operations, complicated incisional hernias • Patients who have illnesses that greatly reduce life expectancy and/or are unlikely to be improved in their medical condition by surgically-induced weight reduction (e.g., cancer). Lifelong medical follow-up after surgery is necessary to monitor adherence to treatment, adverse effects and complications, dietary restrictions, and behavioral health. **[I]**
Follow-Up/Maintenance of Weight Loss	
ACP (2005)	No recommendations offered.
SMOH (2004)	**A** - It is recommended that subjects continue with up to 12 months of the weight maintenance program combining behaviour therapy, a low calorie diet, and exercise, after the initial weight loss treatment. **(Grade A, Level Ib)** **B** - Common behavioral strategies which may enhance successful long-term weight loss maintenance include eating a calorie-restricted, low-to-moderate fat diet, frequent self-monitoring of body weight, recording food intake and physical activity, and maintaining high levels of regular physical activity. **(Grade B, Level III)**
VA/DoD (2006)	**Weight Maintenance and Follow-Up** **Is Patient Losing Weight?**

Patients on diet, exercise, and behavioral therapy who have lost on average 1 to 2 pounds per week should continue with their current treatment until their weight loss goal is achieved. **[B]**

Patients who have lost on average less than 1 pound per week should have their adherence to therapy assessed and treatment plan reevaluated. **[I]**

Obese patients with a BMI $\geq$30 kg/m^2, and overweight patients with a BMI $\geq$27 kg/m^2 and obesity-associated chronic health conditions who fail to achieve adequate weight loss through non-pharmacologic interventions may be candidates for pharmacotherapy with orlistat or sibutramine. **[B]**

Congratulate and Initiate Relapse Prevention/Maintenance

Patients who have met their weight loss goals or have stopped losing weight and are ready to sustain current weight loss should be offered a maintenance program consisting of diet, physical activity, and behavioral support. Weight status should be reevaluated and diet and physical activity should be adjusted so that energy balance is maintained (energy intake is equal to energy expenditure). **[B]**

Providers should continue to maintain contact with patients providing on-going support, encouragement, and close monitoring during the maintenance phase of weight loss to prevent weight regain. **[B]**

Patients who achieve their weight loss goal with a combination of medication, diet, and exercise may be considered candidates to include their medication as a component of their weight maintenance program with continued monitoring of effectiveness and adverse effects. **[B]**

Lifelong follow-up after bariatric surgery is necessary to monitor adherence to treatment, adverse effects and complications, dietary restrictions, and behavioral health. **[I]**

There is no established optimum visit length or duration between maintenance visits, but it seems reasonable to establish a minimum of quarterly follow-up (every three months) for the sustainment of weight loss and more frequently if the patient requests it. **[I]**

Assess Adherence and Modify Treatment

Adherence to weight loss programs should be assessed by periodically measuring the patient's BMI and waist circumference and providing feedback. **[Expert Opinion]**

Patients should be encouraged to record activities by using food logs, exercise logs, and personal diaries to provide structure and allow the

	provider to identify compliance or relapse issues. **[B]**

TABLE 4: BENEFITS AND HARMS	
Benefits	
ACP (2005)	Appropriate pharmacologic and surgical management of obesity in primary care
SMOH (2004)	General approaches and overall benefits: • Successful weight loss reduces risk of obesity-related morbidity and mortality, including cardiovascular diseases, hypertension, diabetes mellitus, sleep apnea, arthritis, cancer, and gall bladder disease. Weight loss has a beneficial effect on glucose tolerance, lipid profile, and blood pressure • Weight loss reduces obesity-related social pressures, including ridicule, discrimination, and job bias, which can result in loss of self-esteem and motivation, depression, and other mental health problems • Successful weight loss reduces obesity-related health costs, both those directly attributable to treatment of associated chronic complications, and indirect costs associated with lost productivity, absenteeism, and loss of future earnings
VA/DoD (2006)	Weight loss improves blood pressure, cholesterol, glycemic control, and obstructive sleep apnea and reduces incident hypertension and type 2 diabetes. Modest weight loss among overweight and obese adults will reduce the incidence and severity of diabetes, a chronic condition that is linked to significant morbidity, mortality, and healthcare costs.
Harms	
ACP (2005)	**Side Effects of Medications** • *Sibutramine:* Modest increase in heart rate and blood pressure, nervousness, insomnia • *Phentermine:* Cardiovascular, gastrointestinal • *Diethylpropion:* Palpitations, tachycardia, insomnia, gastrointestinal • *Orlistat:* Diarrhea, flatulence, bloating, abdominal pain, dyspepsia • *Bupropion:* Paresthesia, insomnia, central nervous system effects • *Fluoxetine:* Agitation, nervousness, gastrointestinal

	Surgery • *Mortality* • *Surgical complications*
SMOH (2004)	**Nutritional Inadequacy of Diets** • Balanced, moderate-fat diet may result in micronutrient deficiencies if food choices are poor. • High-fat, low-carbohydrate diets are high in saturated fat and cholesterol and low in vitamins A, B1, B6, E, folate, calcium, magnesium, iron, potassium, and dietary fibre, and require supplementation. • Very low-fat diets are deficient in B12, E, and zinc. **Complications of Bariatric Surgery** • Bariatric surgery has significant technical issues, complications, and cost, and requires extensive pre- and peri-operative preparation; post-operative lifestyle modifications, as well as follow-up for complications of surgery, are life-long. **Adverse Effects of Medications** • Sibutramine - mild increases in blood pressure and pulse rate, dry mouth, headache, insomnia, and constipation • Phentermine - dry mouth, insomnia, palpitations, euphoria • Mazindol - insomnia, agitation, and dizziness • Ephedrine - adverse psychiatric, autonomic, gastrointestinal, cardiac effects, and death; the easy availability and potential for abuse are major drawbacks ***Note to users from the National Guideline Clearinghouse (NGC):** Ephedrine is not legal for use in the United States. See notice from the U.S. Food and Drug Administration. • Topiramate - paresthesia, diarrhea, somnolence, and dysgeusia • Zonisamide - fatigue • Orlistat - oily diarrhea with urgency in patients noncompliant with reduced-fat diet
VA/DoD (2006)	• Continuing a VLCD for a long period may not be safe. • Potential adverse effects and precautions for drug therapy used in dyslipidemia are provided in Table F-1 in Appendix F of the original guideline document. • There are significant drug or nutrient interactions with anti-obesity agents. See Table F-3 in Appendix F in the original guideline document for a list of known drug interactions to date.

	• Bariatric surgery may be associated with stricture of gastrojejunostomy, gastrointestinal bleeding, marginal ulcer, bowel obstruction, and complications of the LapBand. See Appendix G of the original guideline document for details.

TABLE 5: EVIDENCE RATING SCHEMES AND REFERENCES	
SMOH (2004)	**Grades of Recommendations** **Grade A** (evidence levels Ia, Ib): Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation **Grade B** (evidence levels IIa, IIb, III): Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation **Grade C** (evidence level IV): Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates absence of directly applicable clinical studies of good quality **GPP** (good practice points): Recommended best practice based on the clinical experience of the guideline development group **Levels of Evidence** **Level Ia:** Evidence obtained from meta-analysis of randomised controlled trials **Level Ib:** Evidence obtained from at least one randomised controlled trial **Level IIa:** Evidence obtained from at least one well-designed controlled study without randomisation **Level IIb:** Evidence obtained from at least one other type of well-designed quasi-experimental study **Level III:** Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies **Level IV:** Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

VA/DoD (2006)

Evidence Rating System

Quality of Evidence (QE)

I	At least one properly done randomized controlled trial (RCT)
II-1	Well designed controlled trail without randomization
II-2	Well designed cohort or case-control analytic study, preferably from more than one source
II-3	Multiple time series evidence with/without intervention, dramatic results of uncontrolled experiment
III	Opinion of respected authorities, descriptive studies, case reports, and expert committees

Overall Quality

Good	High grade evidence (I or II-1) directly linked to health outcome
Fair	High grade evidence (I or II-1) linked to intermediate outcome; *or* Moderate grade evidence (II-2 or II-3) directly linked to health outcome
Poor	Level III evidence or no linkage of evidence to health outcome

Net Effect of the Intervention

Substantial:	More than a small relative impact on a frequent condition with a substantial burden of suffering; *or* A large impact on an infrequent condition with a significant impact on the individual patient level.
Moderate:	A small relative impact on a frequent condition with a substantial burden of suffering; *or* A moderate impact on an infrequent condition with a significant impact on the individual patient

	level.
Small:	A negligible relative impact on a frequent condition with a substantial burden of suffering; *or* A small impact on an infrequent condition with a significant impact on the individual patient level.
Zero or Negative:	Negative impact on patients; *or* No relative impact on either a frequent condition with a substantial burden of suffering, or an infrequent condition with a significant impact on the individual patient level.

Strength of the Recommendation

	The Net Benefit of the Intervention			
Quality of Evidence	**Substantial**	**Moderate**	**Small**	**Zero or Negative**
Good	A	B	C	D
Fair	B	B	C	D
Poor	I	I	I	I

A	A strong recommendation that the clinicians provide the intervention to eligible patients. *Good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm.*
B	A recommendation that clinicians provide (the service) to eligible patients. *At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm.*
C	No recommendation for or against the routine provision of the intervention is made. *At least fair evidence was found that the intervention can improve health outcomes, but concludes that the balance of benefits and harms is too close to justify a general recommendation.*

	D	Recommendation is made against routinely providing the intervention to asymptomatic patients. *At least fair evidence was found that the intervention is ineffective or that harms outweigh benefits.*
	I	The conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention. *Evidence that the intervention is effective is lacking, or poor quality, or conflicting and the balance of benefits and harms cannot be determined.*

GUIDELINE CONTENT COMPARISON

The American College of Physicians (ACP), Singapore Ministry of Health (SMOH), and the Department of Veterans Affairs/Department of Defense (VA/DoD) present recommendations for evaluation/diagnosis and treatment of overweight and obesity in adults and provide explicit reasoning behind their judgments.

SMOH and VA/DoD rate the quality of their recommendations and the type of evidence supporting them. ACP specifically refers clinicians to the 2003 USPSTF guideline for screening and counseling recommendations. All of the developers (excluding ACP) rely heavily on the 1998 National Heart, Lung, and Blood Institute's guideline titled "Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults." VA/DoD also drew heavily from the ACP guideline in the development of its recommendations.

Although all the organizations address the issues of evaluation/diagnosis and treatment of overweight and obesity in adults, there are some differences among the guidelines in scope. Recommendations from SMOH, for example, focus on the Asian population, and therefore ethnic differences have been taken into account in calculating BMI cutoffs for overweight and obesity. SMOH also provides guidelines for management of obesity in children and adolescents; the pediatric population is not considered by the other guideline groups. The ACP guideline focuses primarily on the pharmacologic and surgical management of obesity, intending to complement the USPSTF's screening and counseling recommendations.

Areas of Agreement

Evaluation/Diagnosis

The SMOH and VA/DoD guidelines are in general agreement that measurement of BMI, defined as weight in kilograms/height in meters^2 (kg/m^2), is the most reliable and valid method for gauging overweight and obesity in adults (ACP does not address this issue, instead referring to USPSTF recommendations). BMI is also well correlated with degree of risk for obesity-related complications, such as cardiovascular disease. Both of these groups also acknowledge WHO, NHLBI, and other national and international guidelines for classification of overweight and

obesity: a BMI of 25.0 to 29.9 is classified as overweight; obesity is categorized as Class I (BMI > 30 to 34.9), Class II (BMI 35 to 39.9), and Class III (BMI >40). The SMOH guidelines also provide lower cutoffs for the Asian population for all BMI classifications.

The importance of waist circumference as an indicator of cardiovascular and other disease risk is also emphasized by SMOH and VA/DoD. A waist circumference of >88 cm (>35 inches) in women and >102 cm (>40 inches) in men indicates increased risk, independent of BMI. Lower values of waist circumference should be used for Asians (see SMOH recommendations).

Assessment

The two guidelines that provide recommendations on assessment, SMOH and VA/DoD, recommend a clinical assessment be performed, which should include a basic medical history, physical examination, and laboratory tests as indicated. The clinical assessment should screen for comorbid conditions, particularly obesity-related health risks. Other factors to be evaluated include the patient's history of obesity, previous weight-loss attempts, and lifestyle factors, such as dietary and exercise habits.

Both groups also recommend patients undergo a social and psychological assessment to identify behavioral health conditions, such as depression and binge eating, which may affect the success of therapy. There is also agreement that patient motivation to lose weight should be evaluated before initiating therapy.

Dietary Restriction, Physical Activity, and Behavioral Modification

There is concordance between all of the guidelines that the basic treatment strategy for weight loss should be multifaceted, combining dietary restriction, behavior modification, and increased physical activity. All three groups emphasize the need for setting realistic and modest weight-loss goals and for maintaining the loss over the long term.

SMOH and VA/DoD are in agreement that the most important dietary component of weight loss and maintenance is a decrease in caloric intake. Both groups recommend a combination of dietary intervention and physical activity to create a minimum caloric deficit of 500 to 1,000 kcal/day to achieve weight loss of 1 to 2 pounds (.5 to 1 kg) per week. SMOH notes that a diet moderately restricted in total fat, moderate to high in complex carbohydrates, and moderate in protein is the most widely recommended diet. Both groups also agree that moderate levels of physical activity should be performed a minimum of 30 minutes most days of the week.

SMOH states that the aggressiveness of the dietary restriction should correlate with BMI and the presence of any comorbid conditions (i.e., those with higher BMIs or more risk factors should aim for a higher daily energy deficit in their diets). They add that the total calorie intake, rather than the composition of the diet in terms of macronutrients (total fat, carbohydrates, protein), is the most important factor for weight loss. SMOH and VA/DoD both provide recommendations pertaining to LCDs and VLCDs.

Pharmacotherapy

All of the groups agree that the use of pharmacotherapy should generally be reserved for obese patients (BMI greater than 30 kg/m^2). SMOH and VA/DoD agree that pharmacotherapy can also be considered for adults with a BMI greater than 27 kg/m^2 and obesity-related comorbidities. SMOH adds that commensurate BMI thresholds for drug therapy in Asians are lower, at 27.5 and 25 to 27.4 with comorbid conditions, respectively. All groups emphasize that drug therapy should be used only in combination with a reduced-calorie diet, increased exercise, and behavioral interventions.

Recommendations for specific medications differ somewhat. Refer to Areas of Differences below.

Bariatric Surgery

The groups agree that bariatric surgery should be reserved for patients with extreme obesity (generally BMI $\geq$40) who have failed to control weight by other means and who remain at high risk of medical comorbidities. SMOH and VA/DoD agree that surgery can also be considered for adults with a BMI of 35 kg/m^2 or more with one or more obesity-associated chronic health conditions (SMOH notes that commensurate BMI thresholds for surgery among Asians may be 37.5 and 32.5 kg/m^2, respectively).

ACP further adds that patients should be referred to high-volume centers with surgeons experienced in the surgical procedures. VA/DoD specifies that RYGB is the bariatric procedure with the most robust evidence for inducing sustained weight loss for patients with BMI greater than 40 kg/m^2. There is overall agreement that lifelong medical follow-up after surgery is necessary to monitor adherence to treatment, adverse effects and complications, dietary restrictions, and behavioral health.

Maintenance of Weight Loss

There is also concordance among groups that weight loss maintenance requires a combination of dietary restriction, regular sustained physical activity, and self-monitoring.

Areas of Differences

Pharmacotherapy

Guidance regarding specific medications recommended for pharmacotherapy differ somewhat. ACP cites sibutramine, orlistat, phentermine, diethylpropion, fluoxetine, and bupropion as appropriate options, adding that there are no data to determine whether one drug is more efficacious than another. SMOH and VA/DoD, in contrast, assert that the drugs with the widest efficacy and safety data are orlistat and sibutramine. With regard to other medications recommended by ACP, phentermine is acknowledged to have short-term efficacy by both SMOH and VA/DoD; VA/DoD also acknowledges diethylpropion to have short-term efficacy. Neither SMOH nor VA/DoD address bupropion.

With regard to duration of treatment, ACP asserts that there are no long-term (<12 months) studies of efficacy or safety to inform the decision to continue treatment beyond 1 year. SMOH and VA/DoD, however, state that sibutramine and orlistat may be considered as a component of weight maintenance programs for up to 2 years and 4 years, respectively.

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